ATTORNEY DOCKET NUMBER: 2006517-0009

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Caplan *et al.*	Examiner:	Huynh
Serial No.:	10/728,051	Art Unit:	1644
Filing Date:	December 4, 2003	Conf. No.:	9832
Title:	MICROBIAL DELIVERY SYSTEM		

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Applicant appeals to the Board of Patent Appeals and Interferences (the "Board") from the Examiner's rejection of claims 34-45. A Notice to this effect was filed pursuant to 37 C.F.R. § 41.31 on July 27, 2010. Applicant received an electronic acknowledgement receipt indicating that the Notice of Appeal and requisite fees under 37 C.F.R. § 41.20(b)(1) were timely received by the Patent and Trademark Office on July 27, 2010.

Filed herewith is a Petition under 37 C.F.R. § 1.136 for a five (5) month extension of time, from September 27, 2009, up to and including February 27, 2010, to file this Appeal Brief (the "Brief"). Since February 27, 2010, falls on a Saturday, the next succeeding day which is not a Saturday, Sunday, or Federal holiday (*i.e.* Monday, March 1, 2010) shall be considered timely under 37 C.F.R. § 1.7. Also enclosed is an electronic credit card authorization to cover the $1,175.00 fee for a small entity under 37 C.F.R. § 1.17(a)(5) for the Petition and the $270.00 fee for a small entity under 37 C.F.R. § 41.20(b)(2) for the Appeal Brief. Applicant, thus, submits that the Brief is timely submitted on Monday, March 1, 2010.

Real Party in Interest (37 C.F.R. § 41.37(c)(1)(i))

According to the United States Patent and Trademark Office (USPTO) records, an assignment from the inventor (Michael Caplan) to SEER Pharmaceuticals, LLC ("SEER") was recorded in the USPTO on August 11, 2004, at Reel 015670, Frame 0904. An assignment from SEER to Allertein Therapeutics, LLC ("Allertein"), was recorded in the USPTO on September 13, 2006, at Reel 018241, Frame 0373.

A Request to Correct Inventorship under 37 C.F.R. § 1.48(a) to add Hugh A. Sampson, A. Wesley Burks, H. Kim Bottomly and Howard B. Sosin as inventors in the present application was submitted to the USPTO on October 5, 2009 (the "Request"). The Request was accompanied by all of the items required under 37 C.F.R. § 1.48(a), *i.e.*, a statement from each person being added as an inventor under 37 C.F.R. § 1.48(a)(2); a declaration by the actual inventors under 37 C.F.R. § 1.48(a)(3); a written consent of the assignee under 37 C.F.R. § 1.48(a)(5); and payment in the amount of $130.00 as required under 37 C.F.R. § 1.48(a)(4).

Once the Request is granted by the USPTO, and Hugh A. Sampson, A. Wesley Burks, H. Kim Bottomly, and Howard B. Sosin are properly named as inventors in the present application, Hugh A. Sampson will execute an assignment to Mount Sinai School of Medicine of New York University (MSSM), A. Wesley Burks will execute an assignment to University of Arkansas (UARK), and H. Kim Bottomly and Howard B. Sosin will execute assignments to Allertein, and all of these assignments will be recorded in the USPTO.

The correct inventive entity is therefore Michael Caplan, Hugh A. Sampson, A. Wesley Burks, H. Kim Bottomly, and Howard B. Sosin; the owners by assignment are and/or will be Allertein, MSSM, and UARK. Allertein has also licensed the interests of MSSM and UARK, such that Allertein has exclusive rights in this case and is the Real Party in Interest.

Related Appeals and Interferences (37 C.F.R. § 41.37(c)(1)(ii))

Appellant has filed Appeal Briefs for co-pending applications U.S. Serial No. 09/731,375 (still pending); U.S. Serial No. 09/141,220 (now abandoned); U.S. Serial No. 09/455,294; U.S. Serial No. 09/478,668; U.S. Serial No. 09/494,096 (now abandoned); U.S. Serial No. 10/228,806 (issued as U.S. Patent 7,485,708 on February 3, 2009), and some of these Appeal Briefs addressed some issues that overlap with the issues presented here. Appellant has filed Notices of Appeal for co-pending applications U.S. Serial No. 10/728,323 (still pending); and U.S. Serial No. 10/899,551 (now abandoned in favor of continuation application U.S. Serial No. 12/572,599). No other pending appeals or interferences are known to Appellant, Appellant's legal representative, or Appellant's assignee that will directly affect or be directly affected by the Board's decision in this appeal. Similarly, no other pending appeals or interferences are known that may have a bearing on the Board's decision in this appeal.

U.S.S.N. 09/455,294; Appeal No. 2005-1235: Decision of the Board of Patent Appeals and Interferences mailed December 23, 2005, is attached hereto as **Appendix A**, as set forth in 37 C.F.R. § 41.37(c)(1)(x).

Status of Claims (37 C.F.R. § 41.37(c)(1)(iii))

The present application is a divisional of U.S.S.N. 09/731,375, filed on December 6, 2000. The present application was filed on December 4, 2003, with claims 1-36.

Claims 1-33 were cancelled and new claims 34-42 were added by a Preliminary Amendment filed on December 4, 2003.

Claims 1-33 were the subject of a Restriction Requirement mailed March 11, 2005. The Restriction Requirement identified 22 Groups of claims. Appellant responded to the Restriction Requirement on March 24, 2005, noting that claims 1-33 had been canceled and new claims 34-42 had been added in the Preliminary Amendment filed on December 4, 2003. Appellant further noted that claims 34-42 appeared to fall within the subject matter of Group 12 of the Restriction Requirement, made an election of Group 12, and requested that claims 34-42 be examined in the present application.

Claims 34-42 were examined and rejected in an Office Action mailed May 4, 2005. A Response was filed on November 4, 2005, with claim amendments, including amendments adding new claims 43-45. Claims 34-45 were finally rejected in an Office Action mailed on July 18, 2006. A Response was filed on November 1, 2006, with claim amendments. Claims 34-45 were rejected in an Office Action mailed on January 31, 2007. A Notice of Appeal was filed on July 30, 2007. A Request for Continued Examination and Response to the January 31, 2007, Office Action was filed on February 29, 2008, with claim amendments. Claims 34-45 were rejected in an Office Action mailed on April 16, 2008. A Response was filed on October 26, 2008, with no claim amendments. Claims 34-45 were finally rejected in an Office Action mailed on January 26, 2009. A Notice of Appeal was filed on July 27, 2009. Thus, claims 34-45 are pending and stand rejected. The rejection of claims 34-45 is hereby appealed.

Status of Amendments (37 C.F.R. § 41.37(c)(1)(iv))

No amendment was filed subsequent to the final rejection mailed on January 26, 2009. A copy of the claims involved in this Appeal is provided in the **Claims Appendix**.

Summary of Claimed Subject Matter (37 C.F.R. § 41.37(c)(1)(v))

The present inventors developed pharmaceutical compositions that are surprisingly useful for treating or preventing anaphylactic allergic responses to food allergen proteins (see, *e.g.*, p. 3, lines 16-18; p. 6, line 20 to p. 8, line 5; p. 21, lines 2-6; p. 23, lines 26-29; of the Substitute Specification submitted on February 29, 2008, hereinafter the "Substitute Specification"). The pharmaceutical compositions comprise (1) dead *E. coli* comprising at least one Ara h 1, Ara h 2, or Ara h 3 allergen, the amino acid sequence(s) of which has been modified so that the modified allergen has a reduced ability to bind or to crosslink IgE, wherein the modified allergen is encapsulated inside the dead *E. coli*, and (2) a pharmaceutically acceptable carrier (see, *e.g.*, p. 8, line 25 to p. 9, line 8; p. 10, line 20 to p. 11, line 4; p. 13, line 26 to p. 14, line 4; p. 14, lines 11 and 18- 21; p. 15, lines 17-18; p. 16, lines 3-5; p. 21, lines 9-12 and 16-17; p. 22, line 13-23; p. 23, lines 16-19; p. 24, lines 4-6; p. 25, lines 11-14; p. 30, line 11 to p. 34, line 5; p. 37, line 23; Examples 5-9; and p. 66, first row, of the Substitute Specification).

Claims Involved in the Appeal (claims 34-45)

The following is a concise explanation of each independent claim on appeal:

Claim 34 recites a pharmaceutical composition comprising (1) dead *E. coli* comprising at least one modified peanut allergen whose amino acid sequence differs from that of a wild-type peanut allergen that occurs in nature such that the modified peanut allergen has a reduced ability to bind to or cross-link IgE as compared with the wild-type peanut allergen, wherein the wild-type peanut allergen is an Ara h 1, Ara h 2 or Ara h 3 protein with an amino acid sequence that is encoded by the nucleotide sequence of SEQ ID NO:1, SEQ ID NO:2, or SEQ ID NO:3, and wherein the modified peanut allergen has an amino acid sequence substantially identical to that of its corresponding wild type peanut allergen except that at least one IgE epitope has been mutated in the modified peanut allergen such that the modified peanut allergen has the reduced ability to bind or to crosslink IgE, and further wherein the modified peanut allergen is encapsulated inside the dead *E. coli*; and (2) a pharmaceutically acceptable carrier. (see, *e.g.*, p. 8, line 25 to p. 9, line 8; p. 10, line 20 to p. 11, line 4; p. 13, line 26 to p. 14, line 4; p. 14, lines 11 and 18- 21; p. 15, lines 17-18; p. 16, lines 3-5; p. 21, lines 9-12 and 16-17; p. 22, line 13-23; p. 23, lines 16-19; p. 24, lines 4-6; p. 25, lines 11-14; p. 30, line 11 to p. 34, line 5; p. 37, line 23; Examples 5-9; and p. 66, first row, of the Substitute Specification)

Claims 35 -37 recite pharmaceutical compositions as in claim 34, wherein the wild-type peanut allergen is either an Ara h 1 protein with an amino acid sequence that is encoded by the nucleotide sequence of SEQ ID NO:1 (claim 35), an Ara h 2 protein with an amino acid sequence that is encoded by the nucleotide sequence of SEQ ID NO:2 (claim 36), or an Ara h 3 protein with an amino acid sequence that is encoded by the nucleotide sequence of SEQ ID NO:3 (claim 37). (see, *e.g.*, p. 37, line 23; Examples 5-9; and p. 66, first row, of the Substitute Specification)

Claim 38 recites a pharmaceutical composition as in claim 34, wherein the sequence of the modified peanut allergen differs from the sequence of the wild-type peanut allergen by one or more amino acid deletions, substitutions or additions within an IgE binding site of the wild-type peanut allergen. (see, *e.g.*, p. 22, lines 20-24; p. 23, lines 16-24; p. 25, lines 11-14 and 17-23 of the Substitute Specification)

Claim 39 recites a pharmaceutical composition as in claim 38, wherein the sequence of the modified peanut allergen lacks a portion of the wild-type peanut allergen sequence, and wherein said portion includes an IgE binding site. (see, *e.g.*, p. 22, lines 20-24; p. 25, lines 11-14 and 17-23; p. 47, line 27 to p. 49, line 7; and p. 50, line 19 to p. 51, line 7 of the Substitute Specification submitted on February 29, 2008)

Claims 40 and 41 recite pharmaceutical compositions as in claim 34, wherein the modified peanut allergen is located in either the cytoplasm (claim 40) or the periplasm (claim 41) of the dead *E. coli*. (see, *e.g.*, p. 4, lines 13-14; p. 13, line 26 to p. 14, line 4; p. 18, lines 18-21; of the Substitute Specification)

Claim 42 recites a pharmaceutical composition as in claim 34, wherein the modified peanut allergen cannot be detected by antibody binding without disrupting the dead *E. coli*. (see, *e.g.*, p. 4, lines 11-12; p. 11, lines 5-11; and p. 18, lines 14-24 of the Substitute Specification)

Claims 43-45 recite pharmaceutical compositions as in claim 34, wherein the dead *E. coli* was either heat-killed (claim 43) or killed by chemical treatment (claim 44) using a chemical selected from the group consisting of iodine, bleach, ozone, and alcohol (claim 45). (see, *e.g.*, p. 16, lines 3-10 and Example 1 of the Substitute Specification)

Grounds of Rejection To Be Reviewed upon Appeal (37 C.F.R. § 41.37(c)(1)(vi))

The grounds of rejection to be reviewed upon appeal are (referring to §§ **3-7** of the Office Action mailed on January 26, 2009):

(1) Are the pending claims obvious in light of the prior art (see §§ **3-5** of the Office Action mailed on January 26, 2009)? More specifically the Examiner raises the following sub-issues:

(a) Are claims 34-43 obvious in light of PCT Publication Number WO 99/38978 ("the '978 publication") in view of Fenton *et al.* (1995, *J. Natl. Cancer Inst.*, 87:1853-61), Vrtala *et al.* (1995, *Int. Arch. Allergy Immunol.*, 107:290-94), U.S. Patent Number 5,888,799 ("the '799 patent"), U.S. Patent Number 3,097,141 ("the '141 patent"), and Leclerc *et al.* (1990, *J. Immunol.*, 144:3174-82) (see § **4**)?

(b) Are claims 44-45 obvious in light of PCT Publication Number WO 99/38978 in view of Fenton *et al.* (1995, *J. Natl. Cancer Inst.*, 87:1853-61), Vrtala *et al.* (1995, *Int. Arch. Allergy Immunol.*, 107:290-94), U.S. Patent Number 5,888,799 ("the '799 patent"), U.S. Patent Number 3,097,141 ("the '141 patent"), and Leclerc *et al.* (1990, *J. Immunol.*, 144:3174-82), as applied to claims 34-43 (see § **4**), and further in view of PCT Publication Number WO 92/14487 ("the '487 publication") and U.S. Patent Number 6,270,723 ("the '723 patent"), Komanapalli *et al.* (1998, *Appl. Microbiol. Biotechnol.*, 49:766-69), and/or Ingram *et al.* (1980, *J. Bacteriol.*, 144:481-88) (see § **5**)?

(2) Are pending claims 34-45 unpatentable over claims 34-36 and 38-49 of co-pending application U.S. Serial No. 10/728,323 under the judicially created doctrine of obviousness-type double patenting (see §§ **7-8**)?

Argument (37 C.F.R. § 41.37(c)(1)(vii))

As noted above, Claim 34 recites a pharmaceutical composition comprising (1) dead *E. coli* comprising at least one modified peanut allergen whose amino acid sequence differs from that of a wild-type peanut allergen that occurs in nature such that the modified peanut allergen has a reduced ability to bind to or cross-link IgE as compared with the wild-type peanut allergen, wherein the wild-type peanut allergen is an Ara h 1, Ara h 2 or Ara h 3 protein with an amino acid sequence that is encoded by the nucleotide sequence of SEQ ID NO:1, SEQ ID NO:2, or SEQ ID NO:3, and wherein the modified peanut allergen has an amino acid sequence substantially identical to that of its corresponding wild type peanut allergen except that at least one IgE epitope has been mutated in the modified peanut allergen such that the modified peanut allergen has the reduced ability to bind or to crosslink IgE, and further wherein the modified peanut allergen is encapsulated inside the dead *E. coli*; and (2) a pharmaceutically acceptable carrier.

Claims 35-37 specify that the wild-type peanut allergen is encoded by either of SEQ ID NOs: 1, 2, or 3, respectively.

Claim 38 specifies that the sequence of the modified peanut allergen differs from that of the wild-type allergen by one or more amino acid deletions, substitutions, or additions within an IgE binding site of the wild-type peanut allergen.

Claim 39 recites all of the limitations of claim 38, further specifying that the sequence of the modified peanut allergen lacks a portion of the wild-type peanut allergen sequence, and wherein said portion includes an IgE binding site.

Claims 40 and 41 specify that the modified peanut allergen is located in either the cytoplasm or the periplasm, respectively, of the dead *E. coli*.

Claim 42 specifies that the modified peanut allergen cannot be detected by antibody binding without disrupting the dead *E. coli*.

Claims 43-44 specify that the dead *E. coli* was either heat-killed or killed by chemical treatment.

Claim 45 recites all of the limitations of claim 38, further specifying that the chemical is selected from the group consisting of iodine, bleach, ozone, and alcohol.

The claims stand or fall together for grounds for rejection (1)-(2) above, as indicated below:

(1) With respect to sub-issues (a)-(b):

(a) Claims 34-43 stand or fall together.

(b) Claims 44-45 stand or fall together.

(2) Claims 34-45 stand or fall together.

Ground for Rejection (1): Claims 34-45 are not obvious in light of the cited art

Claims 34-45 stand rejected as allegedly being obvious in light of certain prior art references (see § **3-5** in the Office Action mailed January 26, 2009).

Under § **4** of the Office Action, the Examiner rejects claims 34-43 under 35 U.S.C. § 103(a) as allegedly being unpatentable over PCT Publication Number WO 99/38978 ("the '978 publication") in view of Fenton *et al.* (1995, *J. Natl. Cancer Inst.*, 87:1853-61), Vrtala *et al.* (1995, *Int. Arch. Allergy Immunol.*, 107:290-94), U.S. Patent Number 5,888,799 ("the '799 patent"), U.S. Patent Number 3,097,141 ("the '141 patent"), and Leclerc *et al.* (1990, *J. Immunol.*, 144:3174-82).

Under § **5** of the Office Action, the Examiner rejects claims 44-45 under 35 U.S.C. § 103(a) as allegedly being unpatentable over PCT Publication Number WO 99/38978 in view of Fenton *et al.* (1995, *J. Natl. Cancer Inst.*, 87:1853-61), Vrtala *et al.* (1995, *Int. Arch. Allergy Immunol.*, 107:290-94), U.S. Patent Number 5,888,799 ("the '799 patent"), U.S. Patent Number 3,097,141 ("the '141 patent"), and Leclerc *et al.* (1990, *J. Immunol.*, 144:3174-82), as applied to claims 34-43 (see § **4**), and further in view of PCT Publication Number WO 92/14487 ("the '487 publication") and U.S. Patent Number 6,270,723 ("the '723 patent"), Komanapalli *et al.* (1998, *Appl. Microbiol. Biotechnol.*, 49:766-69), and/or Ingram *et al.* (1980, *J. Bacteriol.*, 144:481-88).

With respect to these rejections, claims 34-45 stand or fall together.

These rejections are respectfully traversed for the same reasons that were presented in the Responses to Office Action that were filed on November 1, 2006, July 30, 2007, and October 16, 2008. The Examiner does not appear to have considered Appellant's arguments (see Office Action mailed January 26, 2009). Consideration of this rebuttal and withdrawal of the rejections is respectfully requested.

The § 103 Rejection is an Improper Rejection

As an initial matter, Appellant notes that the present case is on appeal at least in part because it is not possible for Appellant to make constructive progress without *interaction* with the Patent Office. Unfortunately, in the present case, Appellant has been unable to obtain focused, thoughtful, or substantive responses to submitted arguments. Instead, multi-page blocks of text are copied and pasted several times into an Office Action, with few words between them beyond the conclusory statement that the claims are obvious. To illustrate, the Office Action mailed January 26, 2009 ("the Office Action") has the following approximate structure:

A B A' C D A B A' E

A is a block of text in which the Examiner describes her understanding of the *individual teachings* of each of the references (Office Action, p. 2 to p. 5, first paragraph).

B is a single sentence statement that that it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention from the cited references (Office Action, p. 5, second paragraph).

A' is a block of text purporting to explain the motivation behind B, but in fact merely re-listing the individual teachings of the references, substantially as presented in A, although in truncated form (Office Action, p. 5., third paragraph, to p. 6).

C is the statement that Applicant's arguments have been considered but not found persuasive, followed by a *verbatim* presentation of Applicant's points (*i.e.*, the text of Applicant's last Response is simply pasted in to the Office Action. This approach is uniquely confusing, as it creates an impression that the Examiner is *agreeing with* every single point made by Applicant!); (Office Action, p. 6-7, third paragraph).

D is a statement, said to be in "response" to Applicant's argument that the primary reference does not teach what the Examiner had said it teaches, that "one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references" (Office Action, page 7, fourth paragraph). The irony of this statement in light of the rejections is breathtaking.

After **D**, the Office Action begins hopefully, with "Contrary to Applicants' assertion that the WO/38978 does not teach modified allergen, . . . " (p. 7, fifth paragraph) but then, instead of addressing Applicant's point with respect to this reference, the Examiner merely *repeats **A B A'**, almost verbatim*. The Examiner (1) *pastes in exactly the same description of this reference as was present in A*, (2) *pastes in exactly* the statement that that it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention from the cited references as was present in **B**, and (3) *pastes in exactly* the same block of text purporting to explain the motivation behind B, but in fact merely re-listing the individual teachings of the references, substantially as presented in A, although in truncated form, as was present in **A'** (except for a single omission of the word "carrier" from the phrase "vaccine carrier"), but *does not at all* address Applicant's points respecting the errors in that description (Office Action, page 7, fifth paragraph, to p. 10, first paragraph)!

In **E**, the Examiner finally (and inadequately) attempts to address Appellant's arguments from the most recent Office Action response, buried deep with the § 103 rejection (Office Action, p. 10-12). Unhelpfully, this section also includes text relating to an argument made by Appellant in a previous response, which was not made in the most recent response (Office Action, p. 12), suggesting that the Examiner's response is likely assembled from prior responses. Moreover, this section isolates particular claim elements from the rest of the claim (*i.e.*, impermissibly considering the claim *in pieces*, rather than the claim *as a whole*) and impermissibly applies an *individual reference* to an *individual claim element* (Office Action, p. 12-14). This section concludes by citing *KSR v. Teleflex* and declaring that the presently claimed invention was "obvious to try," that there was a reasonable expectation of success, and that the presently claimed invention is therefore obvious (Office Action, p. 14-15), and then discussing *another* argument made by Appellant in a previous response, which argument was not made in the most recent response (Office Action p. 15).

The entire presentation of the Office Action begs the question of whether the Examiner has considered the *actual submissions* made by Appellant and, moreover, presents any responses to such submissions so deeply buried in the context of duplicated or irrelevant text that it is difficult or impossible to achieve any true understanding of the Patent Office position (other than the conclusion that the claims are obvious).

Appellant respectfully submits that this is *not* a legitimate § 103 rejection. The Examiner has not established how one of ordinary skill in the art would take the *collection of references as a whole* and arrive at the present claims. Moreover, the Examiner has made only oblique references to Appellant's previous arguments, but *has not, in fact, substantively addressed* a single one in a manner that can be perceived or appreciated.

Appellant has expended an enormous amount of resources trying to move prosecution forward in this case. Indeed, Appellant has (a) presented numerous arguments, (b) amended the claims several times, and (c) participated in several telephone and in-person interviews, all in an attempt to reach a meeting of the minds with the Examiner. In response to Appellant's sincere efforts, the Examiner continues to issue one Office Action after another, each one virtually identical to the one before. Appellant is *entitled to thoughtful, substantive* prosecution that represents a valid attempt by the Examiner to join Appellant's efforts to move this case toward allowance. See, *e.g.*, MPEP § 701.07(f) ("Where the Appellant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the Appellant's argument and *answer the substance of it*," emphasis added) and MPEP § 7.37 ("The *examiner must address all arguments* which have not already been responded to in the statement of the rejection" emphasis added).

The Claims Are Not Obvious Over the Cited References

Appellant maintains the position that the '978 publication, whether alone or in combination with any of the other 9 cited references, does not teach or suggest a (1) modified (2) Ara h 1, Ara h 2, or Ara h 3 (3) allergen (4) "encapsulated inside" (5) dead (6) *E. coli*, as recited in the present claims.

Appellant points out that a proper obviousness rejection involves review of a set of references "in its entirety, i.e., as a whole" to determine *what the references fairly teach* to a

person of ordinary skill in the art in the *absence* of the teachings of the present specification (MPEP 2141.02, section VI), particularly, what a person of ordinary skill in the art would *understand*. Appellant respectfully submits that one of ordinary skill in the art reading the *entire collection of references* levied in the § 103 rejections would *not* arrive at the presently claimed invention.

Appellant reiterates and incorporates by reference all of the arguments made in previous Responses, *e.g.*, those submitted on November 1, 2006, July 30, 2007, and October 21, 2008. Appellant notes that the Examiner attempted to address some of Appellant's previous arguments on p. 10-12 of the Office Action, but the Examiner's comments demonstrated to Appellant that the Examiner has misinterpreted the teachings of several of the references, including the '978 reference. Appellant, therefore, provides the following observations in an attempt to clarify the teachings of the cited references, and requests that the Board either issue a Notice of Allowance or else otherwise ensure that the Examiner *substantively* addresses *each* of these *specific* observations in a new Office Action

The '978 Publication

The Examiner states that the '978 publication "teaches production of recombinant modified allergen such as modified peanut allergen Ara h 1 (Table 4), modified peanut allergen Ara h 2 (Table 2) and modified peanut allergen [*sic*, Ara h 3] (Table 6)" (p. 2 of the Office Action). The Examiner cites p. 10, lines 10-16, and Tables 4-6 of the '978 publication as supporting this position. The cited sections of the '978 publication do not contain the teaching alleged by the Examiner. For example, Tables 4-6, pointed to by the Examiner, are nothing more than lists of the peptides made, and the amino acid substitutions present in them. In addition, page 10, lines 10-16, the only other teaching pointed to by the Examiner, is a cursory statement that "A modified allergen will typically be made using recombinant techniques. . . . It is also possible to make the allergen synthetically, if the allergen is not too large, for example, less than about 25-40 amino acids in length."

The '978 publication *does* mention (notably, though, in a section *not* pointed out by the Examiner) that modified Ara h 2 can be produced "recombinantly" (page 25, lines 3-12). However, as Appellant has argued in this case and in other related cases (see, *e.g.*, Office Action response submitted on February 29, 2008 in the present case), the '978 publication does not actually *describe* such production, and *certainly* does not describe what kind of cells would be

used. A mere mention that modified allergens can be produced recombinantly *cannot* constitute a description of a composition comprising (1) dead (2) *E. coli* (3) encapsulating modified peanut allergens, as recited in the present claims, let alone of a *pharmaceutical* composition.

The Examiner has asserted that use of urea during the protein purification process described on p. 16 of the '978 publication necessarily means that the produced proteins are "encapsulated within" bacteria. Appellant has pointed out many times that (1) the protein whose purification involved urea in the '978 publication *was not a modified peanut allergen* (it was wild type); (2) that the mere use of urea *does not necessarily mean* that the protein was "encapsulated inside" (urea is a commonly used reagent regardless of location of proteins to be purified); (3) that the protein certainly was not "encapsulated inside" *dead* bacteria, as the process used to kill the bacteria in that purification broke the cells open. The Examiner has never responded to any of these points except to repeat the initial assertions of what the '978 publication teaches. Respectfully, Appellant submits that the Examiner has *completely mischaracterized* teachings of the '978 publication.

Moreover, as Appellant has repeatedly pointed out, the Examiner's approach to the '978 publication improperly tries to isolate certain text and to consider its "teachings" through the lens of the *present specification*, totally apart from the teachings of the '978 publication itself. The *entire purpose* for using urea in the '978 publication is so that the inventors can *isolate* the expressed protein *from E. coli*. The inventors are *not* preparing dead *E. coli* so that the dead *E. coli itself* can be formulated into a pharmaceutical composition, as recited in the present claims. Instead, the inventors in the '978 publication are *physically separating* the produced protein allergens from the *E. coli*. Thus, considering the '978 publication as a whole, it is clear that the inventors of the '978 publication had no appreciation that the produced protein allergens could be useful *except* if and *until* they were isolated from bacterial cells (see, *e.g.*, Examples 4 and 5). The '978 publication, *considered as a whole*, therefore *teaches away from* the claimed invention *as a whole*.

Secondary References

The Examiner takes a similar impermissible approach to each of the secondary references, trying to chose from them a single element that, when abstracted from the rest of their teachings, might be relevant to the present claims. A proper obviousness rejection cannot be assembled with such a strategy. Regardless, even if the Examiner were permitted to pick and

choose only pieces of the cited secondary references, there is no combination of such pieces that in fact renders obvious the present claims.

For example, the Examiner cites Fenton as teaching heat-killed recombinant *E. coli* as useful in a vaccine, but completely ignores the fact that the teachings of Fenton *as a whole* relate to compositions and methods that result in a *mutation-specific immune response* and *teach away* from immunization using cells comprising *modified* allergens (see Response submitted on July 30, 2007).

Fenton teach a pharmaceutical composition comprising dead *E. coli* that express a particular modified Ras protein. Subjects immunized with any given Ras mutant develop immunity *only* to that particular Ras mutant and do not develop immunity to wild type Ras or any other mutant forms of Ras. Fenton describe "lytic activity of Ras-immunized T cells only against tumor cells expressing the same mutant form of Ras used in the immunizations" (page 1859, column 1) and "proliferation of Ras-immune T cells in response to the appropriate mutant Ras peptides but not to wild-type or other mutant Ras peptides" (page 1859, column 2). Fenton further state that "The immunization methods described here likely select for T-cell responses limited to the mutated epitope, since tolerance to wild-type ras sequences (expressed in virtually all cells of the body) would be expected to significantly dampen the response to these sequences as potentially immunogenic epitopes" (page 1860, column 1, first paragraph).

Furthermore, Appellant points out that Fenton, in fact, *teaches away* from immunization using cells comprising *modified* allergens. Considering that the compositions and methods of Fenton are useful for generating a *mutation-specific immune response*, Fenton teaches away from the possibility that immunization with a particular modified allergen can result in protective immunity against wild type allergens or other modified allergens other than the particular one that was used to immunize the individual. One of ordinary skill in the art looking at Fenton would certainly conclude that immunizing an individual with a modified allergen would not result in protective immunity against multiple variants of that allergen (*e.g.*, wild type allergen, other modified allergens). In contrast, the present inventors have described and reduced to practice administration of a modified allergen to an individual in order to immunize the individual against wild type allergen and/or other modified allergen variants. The teachings of Fenton taken *as a whole* are not relevant to the present claims and do not remedy the defects of the '978 publication.

The Examiner cites Vrtala as teaching bacteria transformed with "any cDNA" coding for an allergen (p. 4 of the Office Action), but completely ignores the fact that the teachings of Vrtala *as a whole* relate to compositions comprising *live Salmonella*, not *dead E. coli* (see Response submitted on February 29, 2008). As discussed in the Response submitted on July 30, 2007 (and subsequently ignored by the Examiner), Vrtala acknowledge and extensively discuss the technical and ethical problems associated with use of live allergy vaccines. Vrtala offer *one possible solution* to overcoming these problems, which is to attenuate the live bacteria (*e.g.*, by making a mutation that renders the bacterium less pathogenic or non-pathogenic). Vrtala do not even mention the possibility of using dead bacteria as vaccines. The fact that Vrtala (1) acknowledge and discuss the problem with live vaccines and (2) offer a solution indicate that Vrtala, in fact, *teach away* from any other kind of solution, such as the use of dead *E. coli* as recited in the present claims (see Response submitted on July 30, 2007). The teachings of Vrtala taken *as a whole* are not relevant to the present claims and do not remedy the defects of the '978 publication.

The Examiner cites the '799 patent as teaching use of *E. coli* as an antigen or allergen carrier for treating allergy by inducing tolerance (p. 4 of the Office Action), but completely ignores the fact that the teachings of the '799 patent *as a whole* relate to *live* bacteria.

The '799 patent teaches that when heat-killed *Listeria monocytogenes* (HKL) is mixed with the keyhole limpet hemocyanin antigen (KLH) it acts as an adjuvant that can bias an allergic reaction towards a Th1-type response (*e.g.*, see abstract). There is some discussion of *mixing* HKL with other antigens including allergens in the '799 patent; however, there is no teaching or suggestion of incorporating KLH or other antigens *inside* heat-killed *Listeria monocytogenes* or any other heat-killed microorganism. Appellant does not see how these teachings would motivate the skilled person to prepare dead *E. coli* that include *encapsulated* allergens (let alone modified peanut allergens). The teachings of the '799 patent taken *as a whole* are not relevant to the present claims and do not remedy the defects of the '978 publication.

The Examiner cites the '141 patent as teaching "a method of modifying anaphylactogens while retaining antigenicity of *E. coli*" (p. 4 of the Office Action) but completely ignores the fact that such methods have *nothing to do with* protein allergens that exhibit modified IgE-binding abilities. Indeed, the teachings of the '141 patent *as a whole* relate to "pepsin digest, oxidation,

heat, and ion exchange" as a method of treating bacteria (notably, not bacteria containing therein a protein allergen) to *reduce toxicity* while retaining immunogenicity. Basically, the Examiner (using hindsight reconstruction) added this reference into the mixture because she needed to find a reference that related to *heat-killing* of bacteria, and she chose this one because it describes heat-killing of bacteria, and has some distant relatedness to immunological methods. In other words, the Examiner isolated a claim element, found a reference that mentions of that claim element, isolated that teaching from the rest of the reference, and matched the reference up with the claim. The teachings of the '141 patent taken *as a whole* are not relevant to the present claims and do not remedy the defects of the '978 publication.

The Examiner states that Leclerc teaches "a pharmaceutical composition comprising heat-killed recombinant *E. coli* expressing any antigen of interest wherein the antigen is encapsulated in the periplasm" (p. 11 of the Office Action). Appellant respectfully disagrees with the Examiner's reading of Leclerc. In contrast to the Examiner's assertion, Leclerc does *not* relate to *any* antigen of interest. Instead, Leclerc is relevant only to *viral* antigens. In contrast, the present claims relate to *allergens*, *i.e.*, substances that can elicit an allergic response. Viral antigens are not allergens. Moreover, the present claims recite a specific list of allergens, *none* of which is a viral antigen.

Considering that Leclerc relates only to injection, and that it does not relate to allergens in any way, one of ordinary skill in the art would not find Leclerc relevant to the present claims *as a whole*. The Examiner cannot isolate the "encapsulated within" language from the claims, isolate the encapsulation-via-periplasm concept from Leclerc, match the two up, and throw them into the pot with the rest of the § 103 mixture.

The second § 103 rejection (§ **5** of the Office Action) adds four more references (*i.e.*, the '487 publication, the '723 patent, Komanapalli *et al.*, and Ingram *et al.* The Examiner adds these 4 references to the 6 references discussed above because (1) claims 44 and 45 recite specific ways of killing the *E. coli*, (2) the 6 references discussed above did not provide any description of the such methods, and (3) the 4 additional references describe such methods. None of these references, alone or in combination with any of the cited references, remedies the defects of the '978 publication and other cited references, discussed above. Appellant, therefore, respectfully submits that claims 44 and 45 are allowable over any combination of all 10 cited references.

The Examiner Has Failed To Consider the Claims and Cited References as a Whole

The single *most significant defect* in the Examiner's logic here is that the Examiner is not considering the *claims* as a whole, nor is the Examiner considering the *teachings of the cited references* as a whole. Indeed, the common thread running through all of the points detailed above is that the Examiner is *impermissibly isolating* certain elements of the claims and *matching* them up with other isolated portions of the cited references. Once the Examiner has found a "match" for each of the claim elements, the Examiner simply throws them together in a big pot and concludes that the mixture provides a *prima facie* case of obviousness. This is a textbook case of using impermissible hindsight to construct an obviousness rejection. This is *expressly forbidden* by both the courts and in the MPEP. See, *e.g.*, *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (stating that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning" and "warning against a 'temptation to read into the prior art the teachings of the invention in issue'" (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 36)) and MPEP § 2142.

Conclusion

For all of these reasons, the '978 publication, alone or in combination with the other cited references, cannot teach or suggest pharmaceutical compositions of modified Ara h 1, Ara h 2, or Ara h 3 allergens encapsulated inside dead E. coli. The Examiner cannot continue to ignore these points.

No list of secondary references, however long, is meaningful unless the cited secondary references in fact address the deficiencies of the primary reference. Moreover, the Examiner must take the teachings of the secondary references *as a whole* and may not ignore those portions that inconveniently teach away from the Examiner's intended combination, or from the claimed invention.

Conclusion

Appellant submits that the Examiner (1) has failed to substantiate a proper § 103 rejection, and (2) the claims are not obvious over the cited art. The present claims, therefore, are allowable.

Ground for Rejection (2): Claims 34-45 are not unpatentable over claims 34-36 and 38-49 of co-pending application U.S. Serial No. 10/728,323 under the judicially created doctrine of obviousness-type double patenting

The Examiner has rejected claims 34-45 as being unpatentable over claims 34-36 and 38-49 of co-pending application U.S. Serial No. 10/728,323 under the judicially created doctrine of obviousness-type double patenting. With respect to this rejection all claims stand or fall together. Appellant respectfully refrains from commenting on this rejection until such time as it matures into an *actual* rejection.

In light of the foregoing arguments, Appellant submits that claims 34-45 are not obvious over any of the references (alone or in combination with one another) cited by the Examiner. Appellant respectfully refrains from commenting on the double patenting rejection until such time as it matures into an *actual* rejection. Allowance of these claims is earnestly requested.

Respectfully submitted,

/Katherine Nicole Clouse/
Katherine Nicole Clouse, PhD
Registration Number: 62,750

Choate, Hall & Stewart LLP
Two International Place
Boston, MA 02110
t (617) 248-4903
f (617) 502-5002
nclouse@choate.com
Date: March 1, 2010

Claims Appendix (37 C.F.R. § 41.37(c)(1)(viii))

1-33. (Canceled)

34. (Previously presented) A pharmaceutical composition comprising

dead *E. coli* comprising at least one modified peanut allergen whose amino acid sequence differs from that of a wild-type peanut allergen that occurs in nature such that the modified peanut allergen has a reduced ability to bind to or cross-link IgE as compared with the wild-type peanut allergen, wherein the wild-type peanut allergen is an Ara h 1, Ara h 2 or Ara h 3 protein with an amino acid sequence that is encoded by the nucleotide sequence of SEQ ID NO:1, SEQ ID NO:2, or SEQ ID NO:3, and wherein the modified peanut allergen has an amino acid sequence substantially identical to that of its corresponding wild type peanut allergen except that at least one IgE epitope has been mutated in the modified peanut allergen such that the modified peanut allergen has the reduced ability to bind or to crosslink IgE, and further wherein the modified peanut allergen is encapsulated inside the dead *E. coli*; and

a pharmaceutically acceptable carrier.

35. (Previously presented) The pharmaceutical composition of claim 34, wherein the wild-type peanut allergen is an Ara h 1 protein with an amino acid sequence that is encoded by the nucleotide sequence of SEQ ID NO:1.

36. (Previously presented) The pharmaceutical composition of claim 34, wherein the wild-type peanut allergen is an Ara h 2 protein with an amino acid sequence that is encoded by the nucleotide sequence of SEQ ID NO:2.

37. (Previously presented) The pharmaceutical composition of claim 34, wherein the wild-type peanut allergen is an Ara h 3 protein with an amino acid sequence that is encoded by the nucleotide sequence of SEQ ID NO:3.

38. (Previously presented) The pharmaceutical composition of claim 34, wherein the sequence of the modified peanut allergen differs from the sequence of the wild-type peanut allergen by one or more amino acid deletions, substitutions or additions within an IgE binding site of the wild-type peanut allergen.

39. (Previously presented) The pharmaceutical composition of claim 38, wherein the sequence of the modified peanut allergen lacks a portion of the wild-type peanut allergen sequence, and wherein said portion includes an IgE binding site.

40. (Previously presented) The pharmaceutical composition of claim 34, wherein the modified peanut allergen is located in the cytoplasm of the dead *E. coli*.

41. (Previously presented) The pharmaceutical composition of claim 34, wherein the modified peanut allergen is located in the periplasm of the dead *E. coli*.

42. (Previously presented) The pharmaceutical composition of claim 34, wherein the modified peanut allergen cannot be detected by antibody binding without disrupting the dead *E. coli*.

43. (Previously presented) The pharmaceutical composition of claim 34, wherein the dead *E. coli* was heat-killed.

44. (Previously presented) The pharmaceutical composition of claim 34, wherein the dead *E. coli* was killed by chemical treatment.

45. (Previously presented) The pharmaceutical composition of claim 44, wherein the dead *E. coli* was killed using a chemical selected from the group consisting of iodine, bleach, ozone, and alcohol.

Evidence Appendix (37 C.F.R. § 41.37(c)(1)(ix))

None.

Related Proceedings Appendix (37 C.F.R. § 41.37(c)(1)(x))

U.S.S.N. 09/455,294; Appeal No. 2005-1235: Decision of the Board of Patent Appeals and Interferences mailed December 23, 2005, is attached hereto as **Appendix A**.

APPENDIX A

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GARY A. BANNON,
MICHAEL J. CAPLAN,
HOWARD B. SOSIN,
A. WESLEY BURKS, and
HUGH SAMPSON

Appeal No. 2005-1235
Application No. 09/455,294

ON BRIEF[1]

Before ELLIS, ADAMS, and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-7, 9-29, 31-34, 37, 41, 42, 46-72 and 82-102. Claims 35, 36 and 73-81 were withdrawn from consideration as directed to a non-elected invention, and subsequently cancelled in the After Final Amendment received October 14, 2003, which according to the examiner's Advisory Action (Paper mailed March 1, 2004) was entered for the purposes of

[1] Appellants waived their request for oral hearing. Paper received May 23, 2005.

appeal. Claims 8, 30, 38-40 and 43-45 were canceled in the amendment received October 28, 2002.

Claims 2-7 are illustrative of the subject matter on appeal and are reproduced below:

2. A peptide having an amino acid sequence that is substantially identical to a portion of sequence of an antigen, which portion includes at least one IgE binding site, the peptide amino acid sequence differing from the portion amino acid sequence in that at least one IgE binding site is altered.

3. The peptide of claim 2 wherein the antigen is an anaphylactic antigen.

4. The peptide of claim 1 or claim 2 wherein the antigen is a food antigen.

5. The peptide of claim 4 wherein the antigen is selected from the group consisting of nut antigens, fish antigens, and dairy antigens.

6. The peptide of claim 4 wherein the antigen is selected from the group consisting of peanut antigens, milk antigens, and egg antigens.

7. The peptide of claim 4 wherein the antigen is a peanut antigen.

The references relied upon by the examiner are:

Rogers et al. (Rogers)	5,547,669	Aug. 20, 1996
Sugimoto et al. (Sugimoto)	5,759,572	Jun. 2, 1998
Alving et al. (Alving)	5,820,880	Oct. 13, 1998
Potter	5,871,750	Feb. 16, 1999
Balasubramanian et al. (Balasubramanian)	6,086,899	Jul. 11, 2000
Krieg et al. (Krieg)	6,207,646	Mar. 27, 2001

Ngo et al. (Ngo), Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox, in The Protein Folding Problem and Tertiary Structure Prediction, pp. 497-495, (K. Merz. Jr. et al. eds., Birkhäuser, Boston 1994)

Triozzi et al. (Triozzi), "Effects of a β-Human Chorionic Gonadotropin Subunit Immunogen Administered in Aqueous Solution with a Novel Nonionic Block Copolymer Adjuvant in Patients with Advanced Cancer," Clin. Cancer Res, Vol. 12, pp. 2355-62 (1997)

Burks et al. (Burks), "Mapping and mutational analysis of the IgE-binding epitopes on Ara h 1, a legume vicilin protein and a major allergen in peanut hypersensitivity," Eur. J. Biochem., Vol. 245, pp. 334-39 (1997)

Stanley et al. (Stanley), "Identification and Mutational Analysis of the Immunodominant IgE Binding Epitopes of the Major Peanut Allergen Ara h 2," Archives of Biochemistry and Biophysics, Vol. 342, No. 2, pp. 244-53 (1997)

Fasler et al. (Fasler), "Antagonistic peptides specifically inhibit proliferation, cytokine production, CD40L expression, and help for IgE synthesis by Der p 1-specific human T-cell clones," J. Allergy and Clinical Immunology, Vol. 101, pp. 521-30 (1998)

Skolnick et al. (Skolnick), "From genes to protein structure and function: novel applications of computational approaches in the genomic era," Trends in Biotech., Vol. 18, pp. 34-39 (2000)

GROUNDS OF REJECTION

Claims 1-7, 9-29, 31-34, 37, 41, 42, 82-92 and 94-102 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Stanley.[2]

Claims 1-7, 9-29, 31-34, 37, 41, 42, 82-85, 90 and 94-102 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Burks.[3]

Claims 1, 31-34, 37, 41, 42, 46, 47, 82-87 and 93 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burks in view of Rogers.

Claims 48-54 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burks and Rogers and further in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi.

---

[2] We note that the examiner included claim 30 in the statement of the rejection. Claim 30 was cancelled. See Brief, page 3. Accordingly, we have not included claim 30 in our deliberations.

[3] We note that the examiner included claim 30 in the statement of the rejection. Claim 30 was cancelled. See Brief, page 3. Accordingly, we have not included claim 30 in our deliberations.

Claims 55-63 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burks in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Alving.

Claims 64-72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burks in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Sugimoto.

Claims 1, 31-34, 37, 41, 42, 46-47, 86-87 and 93 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers.[4]

Claims 48-54 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers and further in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi.

Claims 55-63 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Alving.

Claims 64-72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Sugimoto.

Claims 1-7, 9-29, 31-34, 37, 41-42, 46-72 and 82-102 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the scope of the claimed invention.

---

[4] We note that the examiner included claims 38-40 in the statement of the rejection. Claims 38-40 were cancelled. See Brief, page 3. Accordingly, we have not included claims 38-40 in our deliberations.

Claims 1-7, 9-29, 31-34, 37, 41-42, 46-72 and 82-102 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph, as the specification that fails to adequately describe the claimed invention.

Claims 51, 60 and 69 are rejected under 35 U.S.C. § 112, first paragraph, containing, subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

We affirm the prior art rejections. Having disposed of all claims on appeal, we do not reach the merits of the rejections under 35 U.S.C. § 112, first paragraph.

DISCUSSION

Anticipation:

According to appellants (Brief, page 5), the claims stand or fall together. Since all claims stand or fall together, we limit our discussion to representative independent claim 2. As to the rejection over Stanley, claims 1, 3-7, 9-29, 31-34, 37, 41, 42, 82-92 and 94-102 fall together with claim 2. As to the rejection over Burks, claims 1, 3-7, 9-29, 31-34, 37, 41, 42, 82-85, 90 and 94-102 fall together with claim 2. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

As set forth above, claim 2 is drawn to "[a] peptide having an amino acid sequence that is substantially identical to a portion of sequence of an antigen, which portion includes at least one IgE binding site, the peptide amino acid sequence differing from the portion amino acid sequence in that at least one IgE

binding site is altered." As we understand it, the scope of claim 2 is open to include any antigen, including an anaphylactic antigen, and which may also include a food antigen selected from among, nut, fish and dairy antigens. See e.g, claims 3-7. In this regard, we note appellants' assertion (Brief, page 7),

> [t]he specification ... makes perfectly clear that the invention ... encompasses any peptide with reduced IgE binding that includes an altered IgE epitope of any protein antigen, i.e. as required to describe claim 2. The specification also specifically recites relevant subsets of antigens recited in claims 3, 4, 5, 6 and 7....

We also note, appellants assert (Brief, page 9), "[t]he specification presents a precise definition of 'anaphylactic antigen' (see page 6, lines 3-12), and lists all food antigens known as of July 22, 1999 (see pages 73-75), including all nut antigens, fish antigens, and dairy antigens.[5]

> According to appellants' specification (page 1),
>
> The present application ... [claims priority to] co-pending application USSN 09/141,220 filed August 27, 1998, ... [and also] to provisional applications USSN 60/074,590, USSN 60/074,624, USSN 60/074,633, each of which was filed on February 13, 1998. ... [The application further claims priority to] USSN 60/073,283 filed January 31, 1998, [to] PCT/US96/15222 filed September 23, 1996, and [to] ... USSN 08/717,933, filed September 23, 1996. Each of these patent applications is incorporated herein by reference in its entirety.

However, for a number of reasons, the examiner finds (Answer, page 24), "[t]he filing date of the instant claims is deemed to be the filing date of the provisional application 60/073,283 filed 1/31/1998...." Among the reasons identified, the examiner finds (id.),

> (1) the 08/717,933 application, filed Sept[ember] 23, 1996, discloses only the specific peanut peptides of Ara h1 (Table 22 on

[5] Appellants provide no evidence that this list would have been the same as of September 23, 1996, the filing date of their parent application, Application No. 08/717,933.

> page 153 of 08/717,933), and Ara h2 (Table 26 on page 171 of 08/717,933), monoclonal antibody specific to a selected peanut allergen, hybridoma and immunoassay to be used for determining the concentration of a specific allergen (Ara h1) (See summary of invention, pages 6-12, claims of 08/717,933, in particular).

Having found that the claimed invention does not receive the benefit of the 08/717,933 ('933) application, the examiner relies on Burks and Stanley, both published in 1997, to reject the claims as lacking novelty under 35 U.S.C. § 102(a). According to the examiner (Answer, page 26), Burks teach peptides from the anaphylactic peanut antigen Ara hI, while Stanley teach peptides from the anaphylactic peanut antigen Ara h2.

Appellants do not dispute the relevance of the teachings of either Burks or Stanley to the invention set forth in claim 2. Nor do appellants dispute the examiner's characterization of the disclosure of the '933 application. Instead, appellants argue (Brief, page 18), the examiner's reliance on Burks and Stanley is improper because

> the teachings of Burks et al. and Stanley et al. were included near verbatim in priority documents U.S. Serial No. 08/717,933 filed September 23, 1996 (see pp. 135-155, 175, and 178-180 for Burks et al. and pp. 156-174 and 176-180 for Stanley et al., the "1996 filing") and U.S. Serial No. 09/141,220 filed August 27, 1998 (see pp. 7-11 and 16-29 for Burks et al. and Stanley et al., the "1998 filing"). The 1996 filing was specifically made by Appellant in order to protect the teachings of Burks et al and Stanley et al.

From this appellants assert (Brief, page 19), "[i]n the same way that Burks et al. and Stanley et al. could not have been used as 102(a) art against the 1996 filing they cannot be used as 102(a) art against the present application. To do otherwise would negate the very purpose of priority claims." According to appellants (id., emphasis omitted), "[t]he fact that the present application is a

continuation-in-part would only be relevant if the teachings of Burks et al. and Stanley et al. had not been included in the 1996 filing...." We disagree.

As we understand appellants' argument, the '933 application disclosed and claimed two species (Ara h1 and Ara h2) of the generic invention set forth in claim 2 on appeal. These two species are the same as those taught by Burks and Stanley. Therefore, since the '933 application disclosed as much of the claimed invention as the references disclosed, the rejection is improper due to appellants' claim to the benefit of the filing date of the '933 application under 35 U.S.C. § 120. In our opinion, appellants have confused the application of 35 U.S.C. § 120 with that of 37 CFR § 1.131. As set forth in In re Scheiber, 587 F.2d 59, 61-62, 199 USPQ 782, 784 (CCPA 1978),

> The operation of [35 U.S.C.] § 120 differs from the operation of Patent and Trademark Office Rule 131 (37 CFR [§] 1.131). The latter provides an applicant a mechanism for overcoming specific prior art references predating his effective filing date. The applicant need show priority with respect to only so much of the claimed invention as the references disclose, ... or only so much as to render the claimed invention obvious.... Section 120, on the other hand, concerns only an applicant's effective filing date. Unlike Rule 131, § 120 operates independently of the prior art, of which it makes no mention, and it expressly requires an earlier application to disclose the claimed subject matter in compliance with 35 U.S.C. § 112, first paragraph. Thus it is entirely appropriate that the showing required under § 120 differs from that required under Rule 131.

On this record, there is no dispute that claim 2 before us on appeal is not supported by the disclosure in the '933 application. It is elementary patent law that under 35 U.S.C. § 120 a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application, as required by

35 U.S.C. § 112. Mendenhall v. Cedarapids Inc., 5 F.3d 1557, 1566, 28 USPQ2d 1081, 1088-89 (Fed. Cir. 1993) ("A patentee cannot obtain the benefit of the filing date of an earlier application where the claims in issue could not have been made in the earlier application."), cert. denied, 114 S. Ct. 1540 (1994); see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1571, 41 USPQ2d 1961, 1965-66 (Fed. Cir. 1997); Litton Sys., Inc. v. Whirlpool Corp., 728 F.2d 1423, 1438, 221 USPQ 97, 106 (Fed. Cir. 1984); In re van Langenhoven, 458 F.2d 132, 136, 173 USPQ 426, 429 (CCPA 1972). Therefore, despite the fact that appellants' claims are rejected over references that teach no more than is disclosed in their '933 application, that circumstance alone does not entitle appellants to receive benefit of the filing date of the '933 application under 35 U.S.C. § 120 for claims not supported in the '933 application. Accord, Scheiber, F.2d at 62, 199 USPQ at 784.

The relevant inquiry is whether the '933 application satisfies the written description requirement for the presently claimed subject matter. In considering this issue we are mindful that the written description requires that the applicant "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed." [Emphases in original.] Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). The problem which now arises is that although Ara h1 and Ara h2 are disclosed in the '933 parent specification, the full scope of claim 2 before us on appeal is much broader and is not supported by

what is disclosed in the specification of the '933 application. In this regard, we remind appellants that the subject matter as a whole can only have one filing date. In re van Langenhoven, 458 F.2d at 136, 173 USPQ at 429 ("the fact that some of the elements of the breech claims have the support of the parent and foreign applications does not change the result. As to given claimed subject matter, only one effective date is applicable. Whether or not the requirements of section 120 are satisfied is determinative of that date..."). Thus, in the case before us, claim 2 can have only one effective filing date. Since claim 2, as a whole, lacks descriptive support in the '933 specification, it does not receive the benefit of the '933 applications filing date.

For the foregoing reasons we affirm the rejection of claim 2 under 35 U.S.C. § 102(a) as being anticipated by Stanley. As set forth above, claims 1, 3-7, 9-29, 31-34, 37, 41, 42, 82-92 and 94-102 fall together with claim 2.

For the same reasons we also affirm the rejection of claim 2 under 35 U.S.C. § 102(a) as being anticipated by Burks. As set forth above, claims 1, 3-7, 9-29, 31-34, 37, 41, 42, 82-85, 90 and 94-102 fall together with claim 2.

Obviousness:

The examiner presents the following rejections under 35 U.S.C. § 103(a):

1. Claims 1, 31-34, 37, 41-42, 46-47, 82-87 and 93 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burks in view of Rogers.

2. Claims 48-54 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burks and Rogers and further in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi.

3. Claims 55-63 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burks in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Alving.

4. Claims 64-72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burks in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Sugimoto.

5. Claims 1, 31-34, 37, 41, 42, 46-47, 86-87 and 93 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers.

6. Claims 48-54 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers and further in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi.

7. Claims 55-63 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Alving.

8. Claims 64-72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Sugimoto.

In response appellants assert (Brief, page 19), "[e]ach of these obviousness rejections relies on Burks et al. or Stanley et al. as a primary reference. As described above, Burks et al. and Stanley et al. are not available as prior art under [35 U.S.C. §] 103(a). Absent these references each of the obviousness rejection[s] cannot stand."

For the reasons set forth above, we disagree with appellants' assertion that Burks and Stanley are not available as prior art under 35 U.S.C. § 103(a). Since appellants provide no other argument with regard to the obviousness

rejections we find no error in the rejections of record. Accordingly, we affirm the rejection of:

1. claims 1, 31-34, 37, 41-42, 46-47, 82-87 and 93 under 35 U.S.C. § 103(a) as being unpatentable over Burks in view of Rogers.

2. claims 48-54 under 35 U.S.C. § 103(a) as being unpatentable over Burks and Rogers and further in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi.

3. claims 55-63 under 35 U.S.C. § 103(a) as being unpatentable over Burks in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Alving.

4. claims 64-72 under 35 U.S.C. § 103(a) as being unpatentable over Burks in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Sugimoto.

5. claims 1, 31-34, 37, 41, 42, 46-47, 86-87 and 93 under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers.

6. claims 48-54 under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers and further in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi.

7. claims 55-63 under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Alving.

8. claims 64-72 under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Sugimoto.

Enablement:

Having disposed of all claims on appeal, we do not reach the merits of the rejection of claims 1-7, 9-29, 31-34, 37, 41-42, 46-72 and 82-102 under the enablement provision of 35 U.S.C. § 112, first paragraph

Written Description:

Having disposed of all claims on appeal, we do not reach the merits of the rejection of claims 1-7,9-29, 31-34, 37, 41-42, 46-72 and 82-102 under the written description provision of 35 U.S.C. § 112, first paragraph.

New Matter:

Having disposed of all claims on appeal, we do not reach the merits of the rejection of claims 51, 60 and 69 under 35 U.S.C. § 112, first paragraph.

SUMMARY

The rejection of claims 1-7, 9-29, 31-34, 37, 41, 42, 82-92 and 94-102 under 35 U.S.C. § 102(a) as being anticipated by Stanley is affirmed.

The rejection of claims 1-7, 9-29, 31-34, 37, 41, 42, 82-85, 90 and 94-102 under 35 U.S.C. § 102(a) as being anticipated by Burks is affirmed.

The rejection of claims 1, 31-34, 37, 41-42, 46-47, 82-87 and 93 under 35 U.S.C. § 103(a) as being unpatentable over Burks in view of Rogers is affirmed.

The rejection of claims 48-54 under 35 U.S.C. § 103(a) as being unpatentable over Burks and Rogers and further in view of Potter and/or

Krieg and/or Balasubramanian and/or Triozzi is affirmed.

The rejection of claims 55-63 under 35 U.S.C. § 103(a) as being unpatentable over Burks in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Alving is affirmed.

The rejection of claims 64-72 under 35 U.S.C. § 103(a) as being unpatentable over Burks in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Sugimoto is affirmed.

The rejection of claims 1, 31-34, 37, 41, 42, 46-47, 86-87 and 93 under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers is affirmed.

The rejection of claims 48-54 under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers and further in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi is affirmed.

The rejection of claims 55-63 under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Alving is affirmed.

The rejection of claims 64-72 under 35 U.S.C. § 103(a) as being unpatentable over Stanley in view of Rogers in view of Potter and/or Krieg and/or Balasubramanian and/or Triozzi and further in view of Sugimoto is affirmed.

We do not reach the merits of any rejection under 35 U.S.C. § 112, first paragraph.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Joan Ellis
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

DEA/jlb

CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON MA 02110